

DETAILED ACTION

1. The previous office action mailed on 6/10/09 has been vacated and replaced with this new restriction/election requirement. The last restriction/election requirement (mailed 6/10/09) has been vacated and replaced with this new office action because a wrong claim set (filed 8/17/06) was mistakenly examined instead of the amended claim set (amended copy of claims of 8/17/06).

It is noted that applicant will receive a statutory one month of shortened response time under 37CFR 1.134 from the mailing date of this office action.

Election/Restrictions

2. This application contains claims directed to more than one species of the generic invention. The species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The "linker compound" encompasses a large number of structurally and functionally distinct compounds. The compound of formula (1) encompasses a large number of structurally and functionally distinct compounds. As for example, in the compound of formula (1) i.e. $X-Z-(NH-CO)_q-(CH_2)_p-Y$, the group "X", "Y" and "Z" can be selected from a large number of structurally divergent group, which provides a large number of structurally and functionally distinct compound. As for example, the disclosed linker compound (see claim 7) of Formula (107) is structurally, functionally and patentably distinct from the linker compound of Formula (111). Therefore, the compounds encompassed by the compound of formula (1) differ materially in chemical functionality and are structurally diverse and dissimilar compounds, which

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do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Further, the sugar chain of the ligand conjugate of claim 1 comprises a large number of structurally divergent sugar compounds that are structurally and functionally distinct. Also the fields of search are not coextensive. Additionally, besides performing a class/subclass search, the Examiner performs a commercial data base search and an automated patent system (text) search. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Therefore, **Applicants are required in accordance with the practice set forth in MPEP 803.02 to elect a single species of a “ligand conjugate” by electing**

1) a single species of a “linker compound” represented by formula (1),
including an exact definition of each and every substitution on the base molecule,
wherein a single member at each substitution group or moiety is elected and the elected species must read on the compound from which it depends;

2) a single species of a “sugar chain” and

3) a single species of an “aromatic amino group”.

Chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that

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the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holding of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

Upon the election of a single disclosed compound, the scope of the invention, inclusive of the elected compound, will be identified by the Examiner for examination along with the elected species. Moreover, whatever specific compound is ultimately elected, applicants are required to list all claims readable thereon. In the instant case, upon election of a single compound, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound, but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound will be determined. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as

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applicant is informed of the full scope of compounds along with (if appropriate) the process of using or making said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined.

3. The species described above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding technical features for the following reasons: Pursuant to PCT Rule 13.2 and PCT Administrative instructions, Annex B, Part 1 (f)(I)(B)(2), the species are not art recognized equivalents.
4. Should applicant traverse on the ground that the compound are not patentably distinct species, applicant should submit evidence or identify such evidence now of record showing the compound to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.
5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143). Applicant is advised that a reply to this requirement must also include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(1)

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For

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more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shafiqul Haq/
Primary Examiner, Art Unit 1641